Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria™ for liver lesion characterization.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Gastrointestinal Imaging. Liver lesion characterization. Reston (VA): American College of Radiology (ACR); 2002. 8 p. (ACR appropriateness criteria). [29 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Liver lesion

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Gastroenterology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for liver lesion characterization

TARGET POPULATION

Patients with a liver lesion

INTERVENTIONS AND PRACTICES CONSIDERED

1. Ultrasound (US)
2. Follow-up imaging as appropriate or no imaging or procedure required
3. Computed tomography (CT)
    - Nonhelical dynamic contrast-enhanced
    - Helical with arterial and portal venous phase imaging
4. Magnetic resonance imaging (MRI)
    - Contrast-enhanced (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)
    - Without contrast enhancement
5. Nuclear scintigraphy
    - Tc-99m sulfur colloid or Tc-99m RBC
6. Angiography
7. Percutaneous biopsy

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine´s MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

Clinical Condition: Liver Lesion Characterization

Variant 1: Typical benign on initial imaging, no history of malignancy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US	8	
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	7	If classic hemangioma or simple cyst, no further imaging needed.
CT		
Nonhelical dynamic contrast-enhanced CT	6	
Helical CT with arterial and portal venous phase imaging	5	
MRI		
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide,	6	

Radiologic Exam Procedure	Appropriateness Rating	Comments
and mangafodipir)		
MRI without contrast enhancement	4	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	3	
Angiography	2	
Percutaneous biopsy	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: US, ultrasound; CT, computed tomography; MRI, magnetic resonance imaging; RBC, red blood cell

Variant 2: Typical benign on initial imaging, known history of malignancy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	8	If classic hemangioma or simple cyst, no further imaging needed.
US	6	
CT		
Nonhelical dynamic contrast-enhanced CT	6	
Helical CT with arterial and portal venous phase imaging	6	
MRI		

Radiologic Exam Procedure	Appropriateness Rating	Comments
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)	6	
MRI without contrast enhancement	4	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	2	
Angiography	2	
Percutaneous biopsy	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 3: Typical malignant mass on initial imaging.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Percutaneous biopsy	8	
CT		
Helical CT with arterial and portal venous phase imaging	5	
Nonhelical dynamic contrast-enhanced CT	4	
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	4	May be appropriate if indicated clinically--for example, to follow treatment of metastatic disease.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US	4	
MRI		
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)	4	
MRI without contrast enhancement	3	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	2	
Angiography	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 4: Indeterminate on initial imaging, >1 cm, no suspicion or evidence of malignancy or liver disease.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	8	
CT		
Helical CT with arterial and portal venous phase imaging	8	
Nonhelical dynamic contrast-enhanced CT	6	

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI		
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)	8	
MRI without contrast enhancement	5	
US	6	
Percutaneous biopsy	6	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	4	May be of use if classic hemangioma or focal nodular hyperplasia lesion suspected.
Angiography	4	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: US, ultrasound; CT, computed tomography; MRI, magnetic resonance imaging; RBC, red blood cell

Variant 5: Indeterminate mass on initial imaging, >1 cm, known history of malignancy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Percutaneous biopsy	8	
CT		
Helical CT with arterial and portal venous phase imaging	8	
Nonhelical dynamic contrast-enhanced CT	6	
MRI		

Radiologic Exam Procedure	Appropriateness Rating	Comments
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)	8	
MRI without contrast enhancement	5	
US	6	
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	6	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	4	
Angiography	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 6: Indeterminate mass on initial imaging, >1 cm, known or suspected liver disease associated with a high risk of hepatocellular carcinoma (chronic hepatitis, cirrhosis, hemochromatosis, etc.).

Radiologic Exam Procedure	Appropriateness Rating	Comments
Percutaneous biopsy	8	
MRI		
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)	8	
MRI without contrast enhancement	6	

Radiologic Exam Procedure	Appropriateness Rating	Comments
CT		
Helical CT with arterial and portal venous phase imaging	7	
Nonhelical dynamic contrast-enhanced CT	5	
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	5	
US	4	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	2	
Angiography	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 7: Small lesion on initial imaging, <1 cm.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US	8	
Recommend follow-up imaging at an appropriate time interval. No imaging or procedure to characterize the lesion further at this time.	7	
CT		

Radiologic Exam Procedure	Appropriateness Rating	Comments
Helical CT with arterial and portal venous phase imaging	6	
Nonhelical dynamic contrast-enhanced CT	5	
MRI		
Contrast-enhanced MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)	6	
MRI without contrast enhancement	5	
Nuclear Scintigraphy		
Tc-99m sulfur colloid or Tc-99m RBC	2	
Angiography	2	
Percutaneous biopsy	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: US, ultrasound; CT, computed tomography; MRI, magnetic resonance imaging; RBC, red blood cell

Summary

Diagnostic Tests

For characterization of a liver lesion discovered by ultrasound (US), computed tomography (CT), or magnetic resonance imaging (MRI), the following diagnostic studies may be considered:

- Follow-up imaging using the same test as the original study at an appropriate time interval
- Dynamic contrast-enhanced CT (nonhelical, helical, or multidetector helical)
- MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)
- Nuclear scintigraphy (Tc-99m sulfur colloid or Tc-99m RBC)

- Angiography
- Percutaneous biopsy

Note: Research in ultrasound contrast shows considerable promise in characterizing liver lesions, but at the time this document was written, none have been approved for radiologic use in the United States.

When considering possible studies for liver lesion characterization, it is assumed that a logical sequence will be followed. For example, if MRI and biopsy are considered appropriate tests, it is assumed that the biopsy will be done only if the MRI is nondiagnostic. In this case, both studies should be considered "indicated."

Recommendations

Typical Benign Mass: No History of Malignancy. Liver masses with typical imaging features of simple cyst or hemangioma in patients who are not known to have, or are not suspected of having, a malignancy may be classified as benign. Focal fat or focal spared areas in fatty livers can generally be diagnosed when typical features are seen on sonography, noncontrast CT, and most reliably, MRI using in-phase and out-of-phase scanning.

Typical Benign Mass: Known History of Malignancy. Liver masses with typical imaging features of simple cyst or hemangioma in patients who are known to have a malignancy may be considered benign. However, if there is any doubt that the mass is benign, follow-up imaging (using the same test with which the lesion was initially detected) should be performed to make sure there is no change in the lesion appearance. Alternatively, MRI could be performed to help enable a definitive diagnosis. Presence of focal fat can be ascertained with MRI using in-phase and out-of-phase scanning.

Typical Malignant Mass: Lesions with typical sonographic, CT, or MRI features of a malignant mass do not require additional imaging but confirmation with percutaneous biopsy may be appropriate.

Indeterminate Mass: Normal Liver. For indeterminate masses, additional imaging may be required for tissue characterization. In these patients, follow-up imaging is not a practical option due to the need to initiate appropriate treatment. Previously, contrast-enhanced CT was used for liver lesion characterization. There is no information regarding the impact of multidetector helical CT at the time of this writing. Currently, contrast-enhanced MRI is preferred because of its ability to characterize liver lesions and its higher sensitivity and specificity. Alternatively, dynamic helical CT, including arterial and portal venous phase imaging or nuclear scintigraphy may be considered. Magnetic resonance imaging is often preferred, because a single MRI examination is frequently sufficient to differentiate among various types of liver lesions, whereas with nuclear scintigraphy each test allows characterization or exclusion of a single type of liver lesion. Mangafodipir-enhanced MRI may be helpful in distinguishing hepatocellular from nonhepatocellular masses, and iron oxide-enhanced MRI may be useful in distinguishing between benign and malignant masses. However, experience with the use of these contrast agents for liver lesion characterization is limited. For indeterminate liver lesions, a biopsy should be considered if the findings from the additional imaging tests are inconclusive.

Indeterminate Mass: Cirrhotic Liver. Characterization of liver lesions in a cirrhotic liver is best performed with magnetic resonance imaging (MRI), but that characterization is imperfect. Although MRI may sometimes differentiate among regenerating nodules, dysplastic nodules, and hepatocellular carcinoma (HCC), magnetic resonance imaging (like computed tomography [CT] and ultrasound [US]) is best used as follow up to determine if lesions have changed in appearance. Percutaneous biopsy is often needed to make a final diagnosis.

Subcentimeter Lesion: Subcentimeter lesions are difficult to characterize. These small lesions are best evaluated with follow-up imaging because most are benign.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for liver lesion characterization

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as

investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Gastrointestinal Imaging. Liver lesion characterization. Reston (VA): American College of Radiology (ACR); 2002. 8 p. (ACR appropriateness criteria). [29 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 (revised 2002)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria™.

GUIDELINE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Gastrointestinal Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Philip W. Ralls, MD; Jay P. Heiken, MD; Robert L. Bree, MD; Seth N. Glick, MD; James E. Huprich, MD; Marc S. Levine, MD; Michelle L. Robbin, MD; Pablo R. Ros, MD, MPH; William P. Shuman, MD; Frederick Leslie Greene, MD; Loren A. Laine, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It updates a previously published version: Liver lesion characterization. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):193-9.

The ACR Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The anticipated next review date for this topic is 2007.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This summary was updated by ECRI on March 31, 2003. The updated information was verified by the guideline developer on April 21, 2003.

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